

REMARKS

The Official Action dated April 16, 2002 has been carefully considered. Accordingly, the changes presented herewith, taken with the following remarks and the Declaration Under 1.132 submitted herewith, are believed sufficient to place the present application in condition for allowance. Reconsideration is respectfully requested.

By the present Amendment, claim 28 has been cancelled. An abstract of the disclosure has been added. The abstract is supported by the original disclosure and claims. Claim 42 has been added. Support for claim 42 may be found in original claim 28. It is believed that these change do not involve any introduction of new matter, whereby entry is believed to be in order and is respectfully requested.

In the Official Action, the Examiner asserted that claim 28 is not available for action. Specifically, the Examiner asserted that along with a request for filing a Continued Prosecution Application (CPA), Applicant submitted a Preliminary Amendment wherein claim 28 was canceled. Applicants' traverse the position of the Examiner. However, to expedite prosecution of the application, Applicants' have canceled claim 28.

Claims 22-24 and 41 were rejected under 35 U.S.C. §103 as being obvious over Johansson et al, *Metabolism*, Vol 44, No 9, Pages 1126-1129 (September 1995). The Examiner asserted that Johansson et al teach that growth hormone deficient patients are hormone resistant and that the use of recombinant human growth hormone after six months restores insulin sensitivity to baseline values. Therefore, the Examiner asserted that it would have been obvious to one of ordinary skill in the art at the time the invention was made to use growth hormone for treating insulin resistance in a patient having Metabolic Syndrome and abdominal/visceral obesity.

However, as will be set forth in detail below, Applicants submit that the methods defined by claims 22-24 and 41 are nonobvious over and patentably distinguishable from the

teachings of Johansson et al. Accordingly, this rejection is traversed and reconsideration is respectfully requested.

More particularly, claim 22 recites a method for treating a patient for insulin resistance to decrease the insulin resistance, said patient having Metabolic Syndrome comprising Primary Insulin Resistance and abdominal/visceral obesity. The method comprises administering to said patient growth hormone or a functional derivative thereof in an amount effective for decreasing insulin resistance of said patient.

Applicants find no teaching, suggestion or reference by Johansson et al of a method for treating insulin resistance to decrease insulin resistance in a patient with Metabolic Syndrome, as recited in claim 22. Rather, the Johansson et al reference is directed to adult patients who are growth hormone deficient and insulin resistance of such patients. The 1993 Fowelin et al study cited by Johansson et al teaches that after 26 weeks of growth hormone treatment, insulin sensitivity returns to base line values in growth hormone deficient patients. Applicants find no teaching, suggestion, or reference in Johansson et al of the use of growth hormones to decrease insulin resistance in patients who are insulin resistant due to Metabolic Syndrome. Therefore, one of ordinary skill in the art would not have immediately envisaged the use of growth hormones as disclosed by Johansson et al to treat insulin resistance in a patient with Metabolic Syndrome.

Moreover, the Examiner's attention is directed to the Declaration of Dr. Sigbritt A. M. Werner submitted herewith. Dr. Werner serves as a Professor in Endocrinology and Vice President at Karolinska Institute and offers her opinions regarding the state of the art and particularly what Johansson et al teach and suggest to those skilled in the art. Opinion testimony is entitled to consideration and weight as long as the opinion is not on the ultimate legal conclusion at issue, MPEP §716, and opinion testimony regarding what the prior art

taught may be entitled to considerable deference, *In re Carroll*, 202 U.S.P.Q. 571 (CCPA, 1979).

According to paragraph 3 of Dr. Werner's Declaration, she declares based on her experience in the medical fields, and particularly the field of endocrinology, it is her opinion that growth hormone deficient patients are distinct from patients who are not growth hormone deficient. Specifically, growth hormone deficient patients do not produce growth hormones and therefore their hormone levels and their therapeutic response to growth hormone administration differ significantly from the hormone levels and therapeutic response to growth hormone administration in a patient who is not growth hormone deficient. Thus, a therapeutic response to growth hormone administration in a growth hormone deficient patient cannot be used to predict a response to growth hormone administration in a patient who is not growth hormone deficient. Specifically, the effect of growth hormone administration on insulin resistance in a growth hormone deficient patient cannot be used to predict an effect of growth hormone administration on insulin resistance in a patient who is not growth hormone deficient.

Also, as noted at paragraph 4 of the Declaration, based on her experience in the field of endocrinology, it is Dr. Werner's opinion that an individual who has Metabolic Syndrome does not inherently exhibit growth hormone deficiency, and an individual who has growth hormone deficiency does not inherently exhibit Metabolic Syndrome.

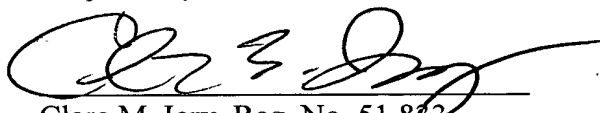
Further, as noted at paragraph 5 of the Declaration, based on her experience in the field of endocrinology, it is her opinion that Johansson et al do not teach or suggest insulin resistance in individuals with Metabolic Syndrome and thus, cannot be used to suggest growth hormone administration to decrease insulin resistance in individuals having Metabolic Syndrome.

References relied upon to support a rejection under 35 U.S.C. §103 must provide an enabling disclosure, i.e., they must place the claimed invention in the possession of the public, *In re Payne*, 203 U.S.P.Q. 245 (CCPA 1979). In view of the failure of Johansson et al to teach, suggest or recognize a method for treating insulin resistance in a patient with the Metabolic Syndrome by decreasing insulin resistance, the reference does not provide an enabling disclosure of the present invention, and therefore does not support a rejection of the claims under 35 U.S.C. §103.

It is therefore submitted that the methods defined by claims 22-24 and 41 are not rendered obvious over Johansson et al and are patentably distinguishable therefrom, whereby the rejection under 35 U.S.C. §103 have been overcome. Reconsideration is respectfully requested.

It is believed that the above represents a complete response to the Examiner's rejection under 35 U.S.C. §103, and places the present application in condition for allowance. Reconsideration and an early allowance are requested.

Respectfully submitted,



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